In the United States Court of Federal Claims

No. 14-266
(Filed Under Seal: February 22, 2024)[*]
(Reissued: March 12, 2024)

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WILBERT L. TOWNSEND, SR.

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

* *

James E. McCollum, Jr., McCollum & Associates, LLC, College Park, MD, for Petitioner.

Ryan Daniel Pyles, Senior Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for Respondent.

OPINION AND ORDER

SOMERS, Judge.

Before the Court is a motion for review of Special Master Dorsey's decision denying compensation under the National Vaccine Injury Compensation Program ("Vaccine Act"), 42 U.S.C. §§ 300aa–10 to 34, to Petitioner, Wilbert L. Townsend, Sr. *See* ECF No. 213-1 ("Motion"). In his motion for review, Petitioner contends that the Special Master erred in denying his claim that the flu vaccine caused him to develop relapsing remitting multiple sclerosis ("MS"). In denying Petitioner's claim, the Special Master concluded that: (1) Petitioner failed to offer a sound and reliable medical theory to support his claim; and (2) Petitioner did not provide preponderant evidence demonstrating that the flu vaccine caused his MS. Petitioner now seeks review of that decision. For the reasons provided below, the Court finds that Petitioner has

[*] On February 22, 2024, the Court issued this opinion and order under seal in accordance with Rule 18(b) of the Vaccine Rules (Appendix B) of the Rules of the U.S. Court of Federal Claims. The Court provided the parties 14 days to proposed redactions. The parties did not propose any redactions, and, accordingly, the Court reissues this opinion and order in its original form with minor stylistic and typographical changes.

not met the high burden imposed under the Vaccine Act to set aside the Special Master's decision and, therefore, denies Petitioner's motion for review.

BACKGROUND

A. Factual History

The Entitlement Decision, *see Townsend v. Sec'y of Health & Hum. Servs.*, No. 14–266 V, 2023 WL 6212496, at *1–22 (Fed. Cl. Spec. Mstr. Aug. 29, 2023) ("Entitlement Decision"), comprehensively detailed the facts, witness testimony, and other evidence relevant to Petitioner's claim; as a result, the Court will only outline the events and evidence relevant to this motion for review.

On October 4, 2011, Petitioner received a flu vaccination at work. *Id.* at *3. In mid-November, Petitioner went to urgent care for hand tremors, sharp bilateral ear pain for one to two days, a lingering cough, and a progressively worsening sore throat. *Id.* During that visit, "[t]he impression was an upper respiratory infection ("URI")[,] and Petitioner was advised to follow-up with primary care." *Id.* Later that month, Petitioner went to the emergency room "with complaints of numbness in arms, neck pain, and trouble walking." *Id.* He was examined by a neurologist and admitted for magnetic resonance imaging ("MRI") and a lumbar puncture. *Id.* The MRI "showed findings compatible with active enhancing demyelinating plaques in the lower cervical and upper thoracic cord extending from C6/7 and T1/2." *Id.* (internal quotations omitted). Petitioner was discharged from the hospital "with the diagnoses of bilateral upper extremity paresthesias, cervical spine foraminal stenosis, ataxia, and hypertension. His MS panel was still pending." *Id.* (citations omitted).

Nine days later, on December 13, 2011, Petitioner was readmitted to the hospital. Upon reexamination, the neurologist's "impression was MS exacerbation, questionable post-vaccination syndrome" and other symptoms. *Id.* at *5. At this time, Petitioner believed that these issues stemmed from his October 4 vaccination. *Id.* at *4. In late December, "[Petitioner] was transferred for acute rehabilitation with a transfer diagnosis including '[b]ilateral upper extremity pain and parethesias secondary to [MS] versus [ADEM] versus post vaccination syndrome.'" *Id.* at *5.

On May 14, 2012, Petitioner sought a second opinion from Dr. Timothy West, a neurologist at the Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Nevada. *Id.* Dr. West reviewed MRIs from April 2012, which showed lesions in the brain and on the spine. *Id.* "Dr. West conclude[d] that Petitioner's 'clinical history and examination are consistent with a diagnosis of aggressive relapsing remitting [MS].'" *Id.* Additional testing confirmed the MS diagnosis. *Id.*

At the entitlement hearing, Petitioner testified that he "has continued to have numbness, pain, balance issues, fatigue, shortness of breath, pressure in his abdomen and sometimes his chest, difficulty urinating and defecating, memory issues, vision problems, problems sitting on hard surfaces for long periods of time[,] muscle weakness, joint stiffness, tightness in feet and ankles, skin dryness particularly in the legs, difficulty stooping or bending, sleep apnea, bed

wetting, erectile dysfunction, and the feeling that [his] body is too heavy for [his] frame." *Id.* at *6 (internal quotations omitted). As of the entitlement hearing, Petitioner still had issues walking and with his gait. *Id.*

B. Hearing Testimony and Expert Reports

The Court will summarize the testimony and reports of the expert witnesses, which are comprehensively recounted in the Special Master's decision. *See id.* at *5–22.

1. Petitioner's First Expert (Dr. Alan Rosenspire, Ph.D.)

Dr. Rosenspire[1] testified at the hearing and submitted five expert reports. He began by explaining how MS attacks the nerves in the central nervous system ("CNS") and the general symptoms seen with MS. *Id.* at *7. Dr. Rosenspire explained that "MS usually begins in the age range of 'mid-twenties to thirties.' Onset 'after 50 is infrequent,' and referred to as 'late onset.'"[2] *Id.* (internal citations omitted). Dr. Rosenspire then acknowledged that the exact cause of MS is unknown. *Id.* Instead, experts generally believe the cause to be multifactorial and triggered in individuals by any combination of one or more environmental factors. *Id.* Although no specific virus has been linked to the development of MS, Dr. Rosenspire's opined that "'epidemiological evidence ha[s] clearly demonstrated that [flu] infections are associated with exacerbation and relapse . . . in those [] afflicted with MS.'" *Id.* at *7 (quoting Pet. Ex. 105 at 3).

Regarding *Althen* prong one, Dr. Rosenspire's opinion is "that molecular mimicry is the mechanism that explains the association between flu viral infection and MS." Entitlement Decision at *7. Dr. Rosenspire cited two main studies to support his opinion regarding the relationship between the flu and MS.[3] The first study stated that molecular mimicry was a "hypothesis put forth which could reconcile the diverse pathology and etiology of MS." *Id.* at *8. Dr. Rosenspire went further to say that there are direct "epidemiological studies [that] have linked both MS and [Guillain-Barré Syndrome ("GBS")] to the influenza infection." Pet. Ex. 105 at 7. However, Dr. Rosenspire conceded that, unlike GBS, there is not a statistically significant connection between the influenza vaccination and MS. *Id.* But Dr. Rosenspire nonetheless reasoned that "GBS is analogous to MS, as both are immune-mediated illnesses associated with molecular mimicry, although GBS is a disease of the peripheral nerves, whereas MS involves the CNS." Entitlement Decision at *9. Moreover "Dr. Rosenspire added that

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[1] Dr. Rosenspire completed "a Ph.D. in biophysical science from SUNY at Buffalo. He then completed a one-year post-doctoral fellowship in the Department of Microbiology at SUNY Buffalo studying cellular immunology and a three-year post-doctoral fellowship at the Sloan Kettering Institute in New York in the immune biology program." Entitlement Decision at *6 (internal citations omitted).

[2] Petitioner filed several articles discussing late-onset MS. *See, e.g.*, Pet. Ex. 20 (Afsaneh Shirani et al., *Multiple Sclerosis in Older Adults: The Clinical Profile and Impact of Interferon Beta Treatment*, 2015 BioMed Rsch. Int'l 1); Pet. Ex. 21; Pet. Ex. 22 (M. Arias et al., *Late Onset Multiple Sclerosis*, 26 Neurología 291 (2011)); Pet. Ex. 23 (V. Martinelli et al*., Late Onset Multiple Sclerosis: Clinical Characteristics, Prognostic Factors and Differential Diagnosis*, 25 Neurological Scis. S350 (2004)).

[3] Jane E. Libbey et al., *Molecular Mimicry in Multiple Sclerosis*, 79 Int'l Rev. Neurobiology 127 (2007). Guo Luo et al., *Autoimmunity to Hypocretin and Molecular Mimicry to Flu in Type 1 Narcolepsy*, 115 Proc. Nat'l Acad. Scis. U.S. E12323 (2018).

because GBS has been added to the [table injury list] and because GBS has an analogous mechanism (molecular mimicry), molecular mimicry will eventually be accepted as the mechanism for MS." *Id.*

Finally, Dr. Rosenspire rejected Respondent's expert's reliance on epidemiology to prove that the flu vaccine does not cause MS. *Id.* at *10. Dr. Rosenspire opined that "studies may show that the flu vaccine is safe, but they do not allow one to conclude that the vaccine is 'safe for everyone.'" *Id.* (quoting Tr. 44). He conceded, however, that the epidemiological studies had "shown that a causal relationship between the flu vaccination and MS is unlikely, but he emphasized that such a relationship was 'certainly possible.'" *Id.* (quoting Tr. 59).

Regarding *Althen* prong two, Dr. Rosenspire concluded that it was more likely than not that the flu vaccine caused Petitioner's MS. *Id.* at *11. A critical reason for his conclusion was Petitioner's age when he was diagnosed with MS, almost 58 years old, and the rarity of late onset MS. *Id.* Dr. Rosenspire disagreed with Respondent's expert who concluded that a URI could have caused Petitioner's MS. *Id.* at *13. Dr. Rosenspire asserted that there was no evidence that Petitioner had contracted a pathogen that could be linked to the onset of MS and argued Respondent's expert put forth no mechanism that could explain a pathogen causing an autoimmune condition. *Id.*

Regarding *Althen* prong three, in his first expert report "Dr. Rosenspire opined that Petitioner's symptoms began approximately ten days following his flu vaccination[,] [which is] the same time frame that the maximal anti-[flu] response is expected." *Id.* (quoting Pet. Ex. 105 at 10) (internal quotations omitted). But "Dr. Rosenspire failed to explain what symptoms he relied on for this opinion." *Id.* at *13. Dr. Rosenspire's testimony stated that Petitioner's symptoms are consistent with molecular mimicry, but he did not "describe the symptoms which he believed occurred two-to-three weeks after vaccination." *Id.*

2. Petitioner's Second Expert (Dr. Todd L. Samuels, M.D.)

Dr. Samuels[4] provided two expert reports and testified at the hearing. He began his testimony by explaining how MS works in the human body. *Id.* Dr. Samuels explained there are two proposed mechanisms that could account for the activation of MS: molecular mimicry and bystander activation. *Id.* Regarding *Althen* prong one, Dr. Samuels' expert report quotes a 2004 Institute of Medicine ("IOM") report that concluded "there is a theoretical basis for [flu] vaccines to induce immune responses that could possibly lead to demyelination." *Id.* (quoting *Inst. of Med., Immunization Safety Review: Influenza Vaccines and Neurological Complications* (Kathleen Stratton et al. eds., 2004)). However, Dr. Samuels "agreed that epidemiology studies indicate that it is unlikely there is a relationship between the flu vaccine and MS." *Id.* at *14.

[4] "Dr. Samuels is a board-certified neurologist." Entitlement Decision at *13. He received his MD from Pennsylvania State University and completed an internship in medicine and psychiatry at the George Washington University Medical Center. *Id.* Dr. Samuels completed a neurology residency at Georgetown University Hospital. *Id.*

Regarding *Althen* prong two, Dr. Samuels testified it was "more likely than not the [flu] vaccine [that] caused [Petitioner's] [MS]." *Id.* Dr. Samuels opined that several reasons supported this conclusion, including Petitioner's age at the time of diagnosis, the aggressive nature of the disease, and the temporal relationship between the vaccination and symptoms. *Id.* Furthermore, Dr. Samuels testified to the atypical nature of Petitioner's case: typical MS cases are younger females with more subtle symptoms. *Id.* But Dr. Samuels could not determine the age or onset of the brain lesions because Petitioner did not have previous studies for comparison. *Id.* Nonetheless, Dr. Samuels testified that the medical findings prove that the flu vaccine caused Petitioner's MS. *Id.* at *15.

Regarding *Althen* prong three, Dr. Samuels' expert report states "[t]here is a logical sequence of cause and effecting showing that the [flu] vaccine was the reason for the injury as well as a proximate temporal relationship between the [flu] vaccine and [Petitioner's] injury." Pet. Ex. 127 at 4.

3. Petitioner's Physician's Letter

Dr. West, one of Petitioner's physicians, wrote a letter in July 2023 "stating that Petitioner 'suffers from a chronic and progressive neurological disease known as [MS].'" Entitlement Decision at *5. His opinion was that "the flu vaccine that he was given on October 4, 2011[,] led to the onset of this central nervous system [(CNS)] demyelinating disease," but he "did not explain the basis for his opinion." *Id.*

4. Respondent's First Expert (Dr. Stephen Mark Tompkins, Ph.D.)

Dr. Tompkins[5] submitted four expert reports and testified at the hearing. Regarding *Althen* prong one, Dr. Tompkins opined that the flu vaccine did not cause Petitioner's MS and based his opinion on the significant body of data showing no association between the flu vaccine and MS. *Id.* at *16. Dr. Tompkins cited several articles to support his conclusion.[6] The articles all have similar findings: that vaccination was not found to increase the risk of developing MS. *Id.* Dr. Tompkins also "opined that it was unlikely that molecular mimicry is a mechanism by which the flu vaccine could cause MS." *Id.* at *17. After reviewing Dr. Rosenspire's opinion, Dr. Tompkins concluded "there [was] a total absence of experimental evidence supporting the idea that influenza vaccination can elicit autoimmune disease." ECF No. 110-1 at 10. Dr. Tompkins also rebutted Dr. Samuels' reliance on the IOM report noting "that both reports

[5] Dr. Tompkins graduated with a B.S. in microbiology from the University of Illinois and received a Ph.D. in immunology and molecular pathogenesis from Emory University. Entitlement Decision at *15. He then completed two post-doctoral immunology fellowships, and "[o]ver the course of his career, Dr. Tompkins has published over 100 [peer reviewed] publications in the fields of immunology and virology." *Id.*

[6] Alexander Hapfelmeier et al., *A Large Case-Control Study on Vaccination As Risk Factor for Multiple Sclerosis*, 93 Neurology E908 (2019); Mia Topsøe Mailand & Jette Lautrup Fredriksen, *Vaccines and Multiple Sclerosis: A Systematic Review*, 264 J. Neurology 1035 (2017); Carola Bardage et al., *Neurological and Autoimmune Disorders After Vaccination Against Pandemic Influenza A (H1N1) with a Monovalent Adjuvanted Vaccine: Population Based Cohort Study in Stockholm, Sweden*, 343 BMJ 1 (2011).

concluded that the 'evidence [was] inadequate to accept or reject a causal relationship' between the flu vaccine and MS." Entitlement Decision at *19 (citing Resp. Ex. N. at 2–3).

Regarding *Althen* prong two, Dr. Tompkins opined that Petitioner's URI—not his vaccination—was more likely than not what caused him to develop MS. *Id.* Dr. Tompkins based his opinion on the "epidemiological data around the association from infection to onset of an autoimmune disease, and in this case [MS]." *Id.* On cross-examination, Dr. Tompkins conceded that no pathogen related to Petitioner's URI was identified. *Id.* Finally, "[r]egarding prong three, Dr. Tompkins agreed that Petitioner's symptoms of MS began following vaccination." *Id.*

5. Respondent's Second Expert (Dr. David N. Alexander, M.D.)

Dr. Alexander[7] submitted three expert reports and testified at the hearing. Regarding *Althen* prong one, Dr. Alexander emphasized that the cause of MS is unknown. *Id.* at *20. In support of this finding, he cited a Farez and Correale (2011)[8] study that found "[n]o significant change in the risk of developing MS after vaccination for . . . [the flu]." Resp. Ex. A, Tab 1. Dr. Alexander cited additional studies that found either no association between vaccines and MS or a potential protective effect of vaccines in MS. Resp. Ex. H Tab 11 at 1–2. Dr. Alexander then opined that molecular mimicry is "not particularly applicable in this case" and that molecular mimicry is not specific to MS. Entitlement Decision at *21. Dr. Alexander also expressed concerns about "Dr. Rosenspire's use of GBS to support his opinions about molecular mimicry in the context of MS." *Id.* Dr. Alexander's most significant criticism, however, was that GBS and MS are very different diseases that "arise from different origins and are embryologically distinct." *Id.* As such, any comparison between the two diseases and their causes is suspect. *Id.*

Regarding *Althen* prong two, Dr. Alexander opined that the flu vaccine did not cause Petitioner's MS, and the vaccine has not been shown to cause MS. *Id.* In reviewing Petitioner's scans, Dr. Alexander suspected the brain lesions were present before vaccination; however, "because Petitioner had no history of symptoms prior to vaccination, and there are no older baseline MRI studies to compare with the post-vaccination MRI studies, Dr. Alexander did not opine that Petitioner's MS predated his vaccination." *Id.* at *22. Finally, while "Dr. Alexander agreed that Petitioner's age at MS onset '[was] uncommon, but not rare,' he did not agree that this fact weighed in favor of vaccine causation." *Id.* The Entitlement Decision does not contain Dr. Alexander's findings regarding prong three.

C. Procedural History

Petitioner filed his petition for compensation under the Vaccine Act on July 7, 2014. ECF No. 1. After the parties filed their evidence, reports, and briefs, the Special Master held a

[7] Dr. Alexander received his M.D. from the University of Minnesota and completed an internal medicine internship at Boston University Medical Center. Entitlement Hearing at *20. Thereafter, he completed a neurology residency at the Neurological Institute of New York, Columbia Presbyterian Medical Center and began teaching and working at the University of California, Los Angeles. *Id.*

[8] Mauricio F. Farez & Jorge Correale, *Immunizations and Risk of Multiple Sclerosis: A Systematic Review and Meta-Analysis*, 258 J. Neurology 1197 (2011).

three-day entitlement hearing from December 6, 2022, until December 8, 2022. *See generally* ECF Nos. 204–06. After post-hearing submissions, the Special Master issued her Entitlement Decision on August 29, 2023, denying compensation. *See* ECF No. 211. After giving the parties an opportunity to propose redactions, the decision was made public on September 5, 2023. ECF No. 212.

Petitioner timely filed his motion for review on September 28, 2023. ECF No. 213. He seeks review of the Special Master's Entitlement Decision based on two principal objections:

1. Petitioner objects and states that the Special Master used an incorrect elevated legal standard in this off-Table Injury case regarding whether Petitioner showed a medical theory causally connecting the vaccination with Petitioner's MS, and a logical sequence of cause and effect showing that the vaccination was the reason for Petitioner's MS.

2. Petitioner objects to all factual findings regarding denying that Petitioner showed a medical theory causally connecting the vaccination with Petitioner's MS, and a logical sequence of cause and effect showing that the vaccination was the reason for Petitioner's MS.

Motion at 2–3. Respondent responded to Petitioners' Motion on October 30, 2023, ECF No. 215, and the Court held oral argument on December 14, 2023, ECF No. 216.

DISCUSSION

A. Standard of Review of a Special Master's Decision

Under the Vaccine Act, this Court has jurisdiction to review a decision of a vaccine special master upon the filing of a motion for review by a petitioner. *See* 42 U.S.C. § 300aa–12(e)(1). In reviewing a special master's decision, the Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa–12(e)(2). In other words, "[u]nder the Vaccine Act, the Court of Federal Claims reviews [a special master's] decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" *Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1355–56 (Fed. Cir. 2007) (citing 42 U.S.C. § 300aa–12(e)(2)(B)).

For factual determinations, the Court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). Rather, "as long as a special master's finding of fact is 'based on evidence in the record that [was] not wholly implausible, [the Court is] compelled to uphold that finding as not being arbitrary or capricious.'" *Id.* (quoting *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000)). Thus, "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *see also Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) ("[O]n review, the Court of Federal Claims is not to second guess [a s]pecial [m]aster[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process."); *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992) (stating that the arbitrary and capricious standard applied to "both fact-findings and fact-based conclusions . . . is a standard well understood to be the most deferential possible"). In short, the Court affords a special master a great deal of deference on factual conclusions and the weight of evidence, and, as a result, a petitioner faces a heavy burden in seeking to overturn a special master's factual and evidentiary determinations.

Under the "not in accordance with law" standard, the Court may review *de novo* statutory or other purely legal issues. *H.L ex rel. A.I. v. Sec'y of Health & Hum. Servs.*, 129 Fed. Cl. 165, 169 (2016); *accord Hines*, 940 F.2d at 1527 (Fed. Cir. 1991) ("The 'not in accordance with the law' aspect of the standard of review . . . [applies in cases in which there is a] dispute over statutory construction or other legal issues."). Finally, the Court may review a special master's discretionary rulings for "abuse of discretion." *Munn*, 970 F.2d at 870 n.10.[9]

B. Petitioner's Burden Under the Vaccine Act

Under the Vaccine Act, a petitioner may seek compensation for two different types of vaccine injuries. First, a petitioner is entitled to compensation "when an injury or condition listed in the Vaccine Injury Table . . . begins to manifest itself within the time specified in the Table for the vaccine in question." *Hines*, 940 F.2d at 1524 (citing 42 U.S.C. §§ 300aa–11(c)(1)(C)(i), 300aa–14(a)). In these so-called "table injury cases," causation is presumed. *Id.* Second, "for injuries not listed in the Table, or which do not occur within the time period

[9] "An abuse of discretion may be found when (1) the court's decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision is based on an erroneous conclusion of the law; (3) the court's findings are clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision." *Simmons v. Sec'y of Health & Hum. Servs.*, 875 F.3d 632, 635 (Fed. Cir. 2017) (citing *Hendler v. United States*, 952 F.2d 1364, 1380 (Fed. Cir. 1991)). However, the abuse of discretion is not frequently applied in vaccine appeals. *See Munn*, 970 F.2d at 870 n.10 (abuse of discretion standard "will rarely come into play except where the special master excludes evidence"); *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 131 (2011) (abuse of discretion is "applicable when the special master excludes evidence or otherwise limits the record upon which he relies"). Here, the Special Master did not exclude evidence or limit the record in any way; therefore, the abuse of discretion standard is not applicable.

stipulated in the Table, the Vaccine Act authorizes recovery only if the petitioner proves actual causation." *Id.* at 1524–25 (citing 42 U.S.C. § 300aa–11(c)(1)(C)(ii)). A petitioner bears the burden of establishing actual causation in a non-table case by a preponderance of the evidence. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010). If a petitioner satisfies his or her burden, then the burden shifts to the respondent to prove by "a preponderance of the evidence that [the petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition." *See* 42 U.S.C. § 300aa–13(a)(1)(B); *accord Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007).

Here, Petitioner's asserted injury—MS allegedly caused by the flu vaccine—is a "non-table" injury. Entitlement Decision at *23. As such, Petitioner must demonstrate, by a preponderance of the evidence, the following three prongs:

> (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed Cir. 2005)

To meet prong one, "a petitioner must provide a reputable medical or scientific explanation that *pertains specifically* to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" *Broekelschen*, 618 F.3d at 1345 (emphasis added) (quoting *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 548–49 (Fed. Cir. 1994)). A petitioner need not establish a plausible medical theory with conclusive evidence. *See Solak v. Sec'y of Health & Hum. Servs.*, No. 14–869–V, 2020 WL 9173158, at *19 (Fed. Cl. Spec. Mstr. Feb. 19, 2020) ("A petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstrations of a specific mechanism, or a generally accepted medical theory."). Still, a theory "that lacks any empirical support will have limited persuasive force." *Caves v. Sec'y of Dep't of Health & Hum. Servs.*, 100 Fed. Cl. 119, 134 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012). Moreover, in evaluating the evidence proffered to meet the preponderance standard, a special master has discretion to determine the relevant weight of the evidence presented. *See Bechel v. Sec'y of Health and Hum. Servs.*, 168 Fed. Cl. 602, 615 (2023).

To satisfy prong two, a petitioner "must show that the vaccine was the 'but for' cause of the harm," *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1356 (Fed. Cir. 2006), often by using facts and medical opinions derived from the petitioner's medical records, *Althen*, 418 F.3d at 1278. However, while medical records and statements of treating physicians should be evaluated and weighed carefully, they are not binding on either a special master or this Court. *See* 42 U.S.C. § 300aa–13(b)(1)(B) ("Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 745 n.67 (2009) ("[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted.").

The third *Althen* prong requires a petitioner to provide a "medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury." *Althen*, 418 F.3d at 1281. Specifically, a petitioner needs to submit "proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The third prong closely links with the first prong because the acceptable timeframe must coincide with a petitioner's theory of how a vaccine can cause the injury. *Id.* In reality, the third *Althen* prong can be broken down into two steps: (1) "establish the timeframe for which it is medically acceptable to infer causation, that is, the timeframe in which symptoms would be expected to arise if the [disorder] was caused by the vaccination," and (2) "show that the onset of [the disorder] occurred during this causation period." *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011).

C. Analysis

As stated above, the Special Master determined that Petitioner failed to meet the required burden of proof for *Althen*'s first two prongs. Accordingly, Petitioner must demonstrate that the Special Master's decision with regard to *both* prong one and two was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law to successfully overturn the Special Master's determination. *See* 42 U.S.C. § 300aa–12(e)(2)(B). Because the Court determines the Petitioner has not demonstrated the Special Master's decision regarding either prong was in error, the Court must deny Petitioner's motion for review.

1. Althen *Prong One*

Althen's first prong requires Petitioner to prove—by preponderant evidence—"a medical theory causally connecting the vaccination and the injury." 418 F.3d at 1278. Such a theory need only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548–49.

Petitioner's medical theory is that the flu vaccine could cause MS via molecular mimicry. Although molecular mimicry is a well-established immunological theory and is often invoked to prove causation in Vaccine Act cases, "the mere mention of it does not constitute satisfaction of the preponderant evidentiary standard." *Loyd ex rel. C.L. v. Sec'y of Health & Hum. Servs.*, No. 16-811V, 2021 WL 2708941, at *31 (Fed. Cl. Spec. Mstr. May 20, 2021), *aff'd*, No. 2022-1371, 2023 WL 1878572 (Fed. Cir. Feb. 10, 2023); *see also McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) ("Merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question." (emphasis omitted)); *Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) ("Petitioners cannot simply invoke the concept of molecular mimicry and call it a day. Rather, they need to offer reliable and persuasive medical or scientific evidence of some kind (whether expert testimony or literature) . . . ." (internal citations omitted) (emphasis omitted)). Instead, "a petitioner needs to cite to evidence, circumstantial or otherwise, suggesting reason to find it plausible that the proposed autoimmune cross-reaction triggered by the relevant vaccine *does*

occur." *Yalacki v. Sec'y of Health & Hum. Servs.*, No. 14-278V, 2019 WL 1061429, at *34 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *aff'd*, 146 Fed. Cl. 80 (2019). In short, "generally opining that molecular mimicry is a causal theory, without more, is insufficient." Entitlement Decision at *25 (citing cases); *see also W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1360 (Fed. Cir. 2013) ("The special master found that molecular mimicry is a well-regarded theory in some contexts, but correctly required additional evidence showing that molecular mimicry can cause the [flu] vaccine to significantly aggravate [MS]." (internal citations and quotations omitted) (citing *Broekelschen*, 618 F.3d at 1345)).

The Special Master found that "Petitioner failed to provide preponderant evidence of a sound and reliable theory to explain how the flu vaccine can cause MS." Entitlement Decision at *24. Importantly, the Special Master did not require Petitioner to make a specific type of evidentiary showing or identify a specific antigen to prove causation because that would be a bar too high. *Id.* ("[T]he undersigned acknowledges that Petitioner need not make a specific type of evidentiary showing or require identification of a specific antigenic trigger for an immune-mediated pathology to prove that a theory is sound and reliable by preponderant evidence."). Rather, after reviewing the record, the Special Master concluded that "the evidence filed in this case [did] not establish that the flu vaccine can cause MS." *Id.* at *26.

In his motion for review, Petitioner's core legal argument—as opposed to his recitation of the facts—is both glaringly brief and incorrectly states the appropriate legal standard under *Althen* prong one:

> Regarding *Althen* prong one, the Special Master's Decision 18-40 is directly contrary to the Vaccine Act and *Althen* because it required Petitioner's theory of causation—molecular mimicry—to be medically or scientifically certain. The Special Master improperly elevated Petitioner's burden of proof for establishing that there is a *plausible theory* that causally connects Petitioner's vaccination and his MS. This was legal error because Petitioner satisfied prong one of *Althen* by providing a medical theory—molecular mimicry—that links the vaccine to MS. *This was a biologically plausible medical theory*. In this case, the Special Master found that "*Petitioner failed to provide preponderant evidence* of a sound and reliable theory to explain how the flu vaccine can cause MS." Decision at 31. *This is a far different and more elevated burden of proof than whether a medical theory is biologically plausible*.

Motion at 16–17 (citations to cases omitted) (emphasis added). Moreover, Petitioner argued that the Special Master discounted his experts' testimony because his experts could not present a specific antigen linked to the injury. *Id.* at 17. Finally, Petitioner provided four quotes from the Special Master's decision, each less than a sentence in length, that he believes demonstrate—without supplying the Court with any argument or explanation—the elevated burden of proof applied to his case. *See id.* (supplying four quotes that, apparently, without any explanation or argument, demonstrate that "[o]ther aspects of the Special Master's prong one analysis demonstrate the elevated and incorrect burden of proof to which Petitioner was held").

Boiled down, Petitioner's argument is that he is only required to show a biologically *plausible* medical theory tying the flu vaccine to MS. *Id.* at 16–17. Petitioner argues that his experts did just that. *Id.* For example, Dr. Rosenspire stated that molecular mimicry can cause *GBS* after vaccination. ECF No. 69–1 at 6–7. While Petitioner has *MS* not GBS, Dr. Rosenspire opined that "[i]n both diseases the connection of the autoimmune response with influenza infection can be explained by a similar mechanism based upon molecular mimicry . . . ." *Id.* at 7. Dr. Rosenspire went on further to "*propose* that like GBS, MS can [be] triggered (through an analogous molecular mimicry grounded mechanism) [by the flu vaccine.]" *Id.* (emphasis added). Dr. Rosenspire also posited that there is "direct experimental support for that idea that the mechanism behind the linkage of MS to influenza infection involves molecular mimicry." *Id.* This, according to Petitioner, is enough to meet *Althen*'s prong one.

Petitioner's argument has several flaws. First, as stated above, Petitioner's core argument is based on an incorrect legal standard. Petitioner is incorrect in stating that all he needed to do was offer "a *plausible theory* that causally connects [his] vaccination [to] his MS." Motion at 16. Rather, Petitioner was required to demonstrate that it is more likely than not that the flu vaccine "can cause" MS. *See* Entitlement Decision *24–27. Indeed, the Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon*, 941 F.3d at 1360(citing cases). Simply put, "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury . . . is not the statutory standard . . . [rather, it is] 'preponderant evidence.'" *Moberly*, 592 F.3d at 1322; *see also Broekelschen*, 618 F.3d at 1350 ("[The] question is whether [petitioner] provided proof by a preponderance of the evidence of a medical theory."); *LaLonde*, 746 F.3d at 1339 ("[S]imply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof."). Accordingly, Petitioner's core argument—that he presented a *plausible* theory that the flu vaccine can cause MS—is necessarily legally insufficient to overturn the Special Master's decision.

Second, Petitioner asserts that his expert's opinion, standing alone, is enough to establish that the flu vaccine can cause MS and that the Special Master erred by not blindly accepting it. But that is not the case. A special master cannot accept an expert's opinion based on *ipse dixit*, as the expert's opinion is "no better than the soundness of the reasons supporting it." *Perreria v. Sec'y of Dept. of Health & Hum. Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994). The Special Master considered the reasons supporting Petitioner's expert's conclusions and was not persuaded. Entitlement Decision at *24–27. The Court is not in a position to "second guess the Special Master's fact-intensive conclusions[,] particularly in cases in which the medical evidence of causation is in dispute." *Bechel*, 168 Fed. Cl. at 614–15 (citations omitted). In reviewing the Special Master's decision, the Court's task is not to reweigh the Special Master's factual findings; instead, the Court must ensure the Special Master acted in accordance with law and provided a rational explanation for her decision. The Special Master did exactly that in her entitlement decision and Petitioner offered the Court little, if any, argument or citation to the record to prove otherwise.

Third, contrary to Petitioner's argument, the Special Master did not require him to show a specific type of evidence or require him to have a theory that is "medically or scientifically certain." Motion at 16. As noted by the Special Master, "[g]iven the state of current scientific

knowledge, there is no way that a petitioner could satisfy such a requirement, especially here, where Dr. Rosenspire conceded that a specific antigen is not known." Entitlement Decision at *24. The Special Master noted that "[t]he literature filed by the parties is replete with statements that the cause of MS is not known." *Id.* at *25. Moreover, the Special Master reviewed studies filed by Respondent that showed no causal association between the flu vaccine and the risk of MS or the risk of an MS relapse. *Id.* at *26. After weighing the evidence, the Special Master made a reasoned determination, and Petitioner has offered nothing to clear the high bar required to disturb that determination.

Although the Court understands Petitioner's frustration with the perceived tension between providing a plausible medical theory and providing preponderant evidence of such a theory, *see Bechel*, 168 Fed. Cl. at 618–19 (explaining the potential confusion and rejecting the idea that *Moberly* introduced confusion regarding the standard for *Althen* prong one), Petitioner has not demonstrated error in the Special Master's determination that Petitioner failed to show the necessary causal relationship between the flu vaccine and MS. While Petitioner and his experts put forth the well-established medical theory of molecular mimicry as the mechanism through which the flu vaccine could cause MS, Petitioner failed to point to anything to demonstrate error on the Special Master's part in finding that Petitioner did not sufficiently tie the flu vaccine to MS through molecular mimicry.[10] As the government noted in its response, "[i]n short . . . the evidence was too generalized to pertain specifically to the petitioner's case." Response at 9 (internal quotation marks deleted).

The Special Master considered the evidence and made a reasoned conclusion that Petitioner failed to carry his burden under *Althen* prong one. Petitioner has not proved that the Special Master's determination was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. The Special Master "considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision, [and as such,] reversible error [was] extremely difficult to demonstrate." *Hines*, 940 F.2d at 1528. Although Petitioner hoped the Special Master would accord his evidence more weight and find he offered preponderant evidence in support of his medical theory, the fact that the Special Master disagreed is not reversible error. Here, as required, the Special Master carefully reviewed the evidence, drew credible inferences, and articulated a rational basis for her determination. As such, the Court will not disturb that determination.

[10] Petitioner also argues that the Special Master's statement that "[g]iven the state of current scientific knowledge, there is no way that a petitioner could [provide a specific antigen], especially here, where Dr. Rosenspire conceded that a specific antigen is not known[,]" is internally inconsistent and legally incorrect. Motion at *17. The Court does not agree. The Special Master was simply pointing out that given current medical knowledge makes it impossible for a petitioner to show a specific cause of MS because it is not known. This does not mean a petitioner could never show by a preponderance of the evidence a medically plausible theory tying a vaccine to MS. The Special Master acknowledged that molecular mimicry is an accepted medical theory, but "generally opining that molecular mimicry is a causal theory, without more, is insufficient." Entitlement Decision at *25 (quoting *W.C.*, 704 F.3d at 1360).

2. Althen *Prong Two*

Althen's second prong requires a petitioner to demonstrate that the vaccine was the "but-for" cause of the injury. 418 F.3d at 1278. Medical records, or testimony by a physician, are persuasive but not binding upon a special master:

> [a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

42 U.S.C. § 300aa–13(b)(1)(B). Instead, a petitioner must—by a preponderance of the evidence—show a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. In determining if a petitioner has met his or her burden, a special master considers the record as a whole, including all relevant evidence cited by both parties throughout the proceedings. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1327–28 (Fed. Cir. 2016); *see also de Bazan*, 539 F.3d at 1353 ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence of a requisite element of the petitioner's case-in-chief.").

The Special Master first found that, because Petitioner failed to prove *Althen* prong one, he could not prove *Althen* prong two. Entitlement Decision at *28. The Special Master, however, did not stop there, determining that "even if Petitioner had proved *Althen* prong one, . . . Petitioner has failed to show by preponderant evidence that there is a logical sequence of cause and effect showing Petitioner's flu vaccine caused his MS." *Id.* In so deciding, the Special Master found Petitioner's expert's opinion was too speculative because it "was based on his 'guess.'" *Id.* (citing Tr. 60–61). Going even further, the Special Master found "Dr. Rosenspire's opinion is not supported by medical literature." *Id.* at *29. Finally, the Special Master rejected the letter from Petitioner's physician because he "did not explain or describe the basis for his opinion." *Id.* Because the letter did not provide a foundational basis, "it does not provide preponderant evidence of causation, especially given the lack of evidence that the flu vaccine can cause MS." *Id.* Finally, the Special Master found another possible condition, Petitioner's URI, could have caused his MS. *Id.* at *30. However, even without the URI, the Special Master still would have held that Petitioner did not prove a logical sequence of cause and effect. *Id.*

Petitioner, on review, takes issue with the Special Master's aforementioned analysis. Motion at 18. Petitioner argues that he "took the vaccine and shortly thereafter exhibited symptoms of MS, which have been confirmed by Petitioner's treating physician and others" and that the Special Master's mention of an alternative cause, the URI, tainted the analysis. *Id.* At best, this argument is conclusory. While the Petitioner was not required to disprove alternative causes, *see Walther*, 485 F.3d at 1149–52, the Special Master noted that her decision would have been the same regardless of the URI. Entitlement Decision at *30. In reviewing evidence, a special master can consider alternative causes regardless of whether a petitioner has carried his

or her burden. *See Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d. 1349, 1356–58. In so doing, the Special Master did not commit reversible error.

Notably, nowhere did the Special Master "impermissibly elevate[] Petitioner's burden of proof regarding his prima facie showing." Motion at 18. As the government points out in its response, "the fact that the onset of MS followed vaccination is not in and of itself proof of anything." Response at 15. Petitioner was required to provide preponderant evidence that the flu vaccine was the but-for cause of his MS. The Special Master determined he failed this requirement. For example, Petitioner's second causation argument hinged on the fact that he suffered from late-onset MS. Entitlement Decision at *28. But, as the Special Master found, "none of the articles suggest that the pathogenesis of late-onset MS differs from early-onset MS, or that late-onset MS is likely to be vaccine-related." *Id.*

On review, Petitioner points to nothing to show that the Special Master's decision on this prong is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. While Petitioner may not have reached the same conclusion as the Special Master, the Special Master considered all the evidence before her and found that the record did not preponderantly establish that Petitioner's MS was caused by the flu vaccine he received. It is not reversible error that the Special Master was unconvinced by a contested theory of age-based onset MS, or an expert's "guess," or an unexplained physician's letter regarding the cause of the MS. As such, Petitioner has failed to demonstrate that with regard to prong two the Special Master's determination was in error.

CONCLUSION

For the foregoing reasons, the Court finds that the Special Master's Entitlement Decision with regard to *Althen* prongs one and two was reasonable. Accordingly, Petitioners' Motion for Review is **DENIED,** and the decision of the Special Master is **SUSTAINED**. In addition, Petitioner's motion for attorney's fees, ECF No. 217, is **REMANDED** to the Special Master. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Zachary N. Somers
ZACHARY N. SOMERS
Judge